

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>UNITED STATES OF AMERICA</b>	:	
	:	
<b>v.</b>	:	<b>No.</b>
	:	
<b>AMERICAN HEALTH CARE, INC. and</b>	:	
<b>EDWARD LETKO</b>	:	

**COMPLAINT**

The United States of America, by its attorneys, Zane David Memeger, United States Attorney for the Eastern District of Pennsylvania, Margaret L. Hutchinson, Assistant United States Attorney, and Michael S. Blume, Assistant United States Attorney, brings this civil action under the fraud injunction statute, 18 U.S.C. § 1345, and Federal Rule of Civil Procedure 65. In support of the complaint, the United States alleges as follows:

1. This is a civil action initiated by the United States of America to enjoin fraud based on probable cause to find violations of 18 U.S.C. § 1343 (wire fraud), for a permanent injunction to prevent continuing and substantial injury to the victims of the fraud, and for such other relief as justice requires. The United States of America alleges that defendants AMERICAN HEALTH CARE, INC. and EDWARD LETKO executed a scheme and artifice to defraud consumers who purchased diabetic test strips not meant for sale in the United States in violation of 18 U.S.C. § 1343.

2. This Court has jurisdiction of this action pursuant to 18 U.S.C. § 1345 (fraud injunction statute) and 28 U.S.C. §§ 1331 (federal question jurisdiction) and 1345 (actions brought by the United States as plaintiff).

3. Venue is proper in this district because the defendants conduct business in this district, and send interstate wire transmissions in furtherance of the scheme in and to this district.

### **FACTS**

#### **A. The Defendants.**

4. The defendants are American Health Care, Inc. and its President Edward Letko. American Health Care, Inc. is a New Jersey corporation with its principal place of business at 304 Park Avenue South, New York, New York.

#### **B. Diabetic Test Strips.**

5. American Health Care, Inc. distributes diabetic test strips.

6. Diabetic test strips are small, flat plastic medical devices. A test strip user places a drop of his blood on the test strip, which he then inserts into a meter. The meter measures blood glucose levels by reading the way chemicals in the test strip react with the blood.

7. Test strips are therefore essential in diabetic care. They help a diabetic determine how much insulin he may need to regulate the glucose in his blood.

8. Manufacturing companies typically sell test strips in boxes of 50 or 100. The packaging generally contains important information about the strips. The box itself contains a code, which must be entered into the meter to calibrate it. The box also contains a lot number. (Under federal law, the “label” – or outside of the test strip box – must include a lot number.) Inside the box is an insert – the “labeling,” which is commonly folded pieces of paper – that contains directions for using the strip. The insert

often includes a toll free telephone number for the consumer to use to contact the manufacturer for further information about the test strips.

9. Manufacturers produce test strips in plants around the world. Not all test strips are intended for sale in the United States, in part because of different blood measurement standards used in different countries. What is more, test strips meant for sale outside of the United States are not necessarily subject to the same oversight of storage and transport conditions as those strips meant for sale in the United States. The test strips are temperature sensitive, and their performance could be affected by improper storage and transport.

10. When a test strip box – and/or any part of the test strip labeling – contains language indicating that the test strips are not meant for sale in the United States, that language may not be altered or obscured.

C. Lot Numbers for Test Strips

11. As noted, a lot number will be on a diabetic test strip box.

12. Each batch of test strips manufactured at the same time and in the same plant is assigned a unique lot number.

13. Lot numbers become vitally important in the case of any problem with the test strips. Manufacturers and government safety agencies – like the Food and Drug Administration – communicate with the public by referencing lot numbers. That is, if there is a problem with test strips and/or if there is a need to recall test strips, manufacturers and the government agencies will notify the public by referencing the lot number, i.e., by noting that test strips containing a specific lot number are defective.

14. Manufacturers maintain web sites and toll free telephone numbers to communicate with consumers. Consumers can check the safety of the test strips they purchase by comparing the lot numbers on the boxes of their test strips against any problematic lot numbers listed on manufacturer web sites. They can also call the toll free numbers to check for any problems with their test strips.

15. Test strip boxes not intended for sale in the United States do not share lot numbers with test strip boxes intended for sale in the United States.

16. If there is a problem with test strips not intended for sale in the United States, the manufacturer's web sites and toll free telephone numbers meant for United States consumers may not list the lot numbers for the problematic test strips.

D. The Gray Market and American Health Care

17. There is a gray market for diabetic test strips. The gray market exists, in part, because the price for diabetic test strips is higher in the United States than it is in foreign countries.

18. In the gray market, distributors purchase genuine diabetic test strips that are intended for sale outside of the United States. The distributors can obtain such test strips at relatively low prices. The distributors then ship the test strips to the United States and re-sell them, often to wholesalers or other distributors, at prices lower than those the purchaser would have to pay to obtain test strips meant for sale in the United States. The test strips ultimately make their way, through the stream of commerce, to retail outlets, like local pharmacies.

19. American Health Care, led by its President Edward Letko, operated in, and still does operate in, the gray market for diabetic test strips.

20. As part of its business – beginning in or about, at least, November 2004 and continuing until, at least, in or about June 2006 – American Health Care purchased diabetic test strips, not intended for sale in the United States, in markets overseas and then imported the test strips into the United States.

21. American Health Care then sold those test strips to purchasers in the United States.

22. It was a common practice of American Health Care to fax solicitations from New York to pharmacies in states around the country, including to pharmacies in the Eastern District of Pennsylvania. The faxed solicitations would advertise the products that American Health Care had for sale.

E. The Misleading Sale of Gray Market Test Strips

23. In selling gray market test strips within the United States, the defendants took steps to mislead purchasers about the nature of the test strips that they were selling.

24. As noted above, boxes of test strips not meant for sale in the United States may include language, on the boxes themselves, stating that the test strips were not meant for sale in the United States. That language may not be altered or obscured.

25. It was a practice of American Health Care to place stickers and/or labels on boxes of test strips – not meant for sale in the United States – to obscure language on the boxes stating that the test strips were not meant for sale in the United States.

26. American Health Care placed such stickers and/or labels on the boxes of test strips in order to facilitate the sale of the boxes, at the retail level, to individual consumers in the United States. Many consumers would choose not to purchase the boxes if they were aware that the boxes were not meant for sale in the United States.

27. As a result of these actions to alter boxes of diabetic test strips, individual consumers in the United States purchased test strips without knowing that the test strips were not meant for sale in the United States. The individual consumer was therefore purchasing test strips unaware of a potential risk, a risk that would be material to any decision he might make to purchase the test strips in the first place.

28. Should there be a problem with or recall of the lot numbers associated with the test strips that the consumer purchased, the consumer in the United States would find it difficult if not impossible to learn about that problem or recall. That is so because:

A. The lot numbers associated with the test strips he had purchased likely would not appear on the manufacturer's United States web site, as typically the lot numbers would often only appear on web sites meant for foreign consumers.

B. The toll-free number that would come with some of the test strips meant for sale outside the United States would only work outside of the United States.

C. Even if the United States consumer reached the manufacturer – using a United States telephone number – he might not get the answers he needs. The United States operator might not be aware of any problems with the lot numbers associated with the test strips he purchased; those lot numbers were not meant for United States consumers after all.

#### **PRAYER FOR RELIEF**

29. The United States restates paragraphs 1 through 28, inclusive, as if fully set forth herein.

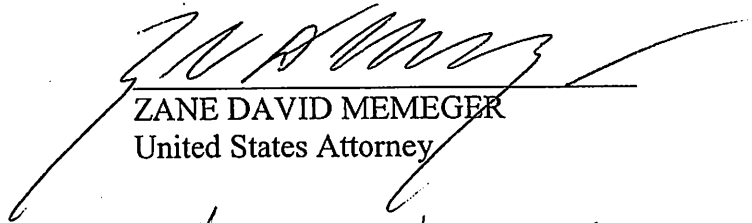
30. The defendants committed the acts alleged in this complaint knowingly and willfully, intending to defraud purchasers in the manner described above.

31. The defendants, having devised a scheme or artifice, as described above, to defraud, and/or for obtaining money or property by means of false or fraudulent pretenses, transmitted and/or caused to be transmitted by means of wire communication in interstate commerce the faxed solicitations, described above, for the purpose of executing such scheme or artifice.


32. The defendants have engaged in and are about to engage in violations of 18 U.S.C. § 1343 (wire fraud).

33. In order to prevent this injury from occurring or recurring, the defendants should be enjoined pursuant to 18 U.S.C. § 1345 and/or Federal Rule of Civil Procedure 65 from engaging in this fraudulent activity and should be subject to other equitable relief.

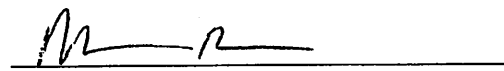
WHEREFORE, plaintiff, the United States of America, prays that this Court, pursuant to 18 U.S.C. § 1345, Federal Rule of Civil Procedure 65, and/or its inherent equitable powers, permanently enjoin the defendants from such unlawful activity and grant such other and further relief as is just and proper to prevent injury to the public.



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